

# Notice of Allowability

Application No.

10/602,752

Applicant(s)

ROBL ET AL.

Examiner

Evelyn Huang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to \_\_\_\_\_.
2. ☒ The allowed claim(s) is/are 47, 48 and 50-59.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Evelyn Huang  
Primary Examiner  
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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 21-40, 46, drawn to a pharmaceutical composition comprising multiple active ingredient, classified in class 514, subclass various dependent on the species elected.
  - II. Claims 47, 48, 50-60, drawn to an intermediate compound, classified in class 546, subclass 89, its process of making and process of use.

Invention I is drawn a multiple active ingredient composition and its method of use. Invention II is an intermediate compound, classified in class 546, subclass 89, its process of making and process of use. These inventions are patentably distinct from each other as they have acquired a separate status in the art because of their recognized divergent subject matter. A reference anticipating one Group I invention would not render obvious the Group II invention. The search is not co-extensive and is therefore burdensome. Since the search required for Group I is not required for the Group II, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Mr. Rodney on 3-25-2004, a provisional election was made to prosecute the invention of Group II, claims 47, 48, 50-60. Claims of Groups I are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***EXAMINER'S AMENDMENT***

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

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1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Rodney on 3-30-2004. During the interview, the examiner suggested deleting the non-elected claims 21-40, 46 without prejudice to filing of divisional applications. The examiner also suggested amending the priority claims and amending the process claims 50-60 to be of the same scope as the allowable compound claim 47 to place the application in conditions for allowance.

The specification has been amended as follows:

Page 1, line 3, after 'This application', insert -- is the divisional of U.S. Application 10/007,407, filed on 12-4-2001, now U.S. Patent No. 6,627,636, which --

The claims have been amended as follows:

- a. Cancel the non-elected claims 21-40, 46 without prejudice to filing divisional applications.
- b. Claim 50,
  - Definition of R7b and R7c, lines 3-8, delete 'or R7b and R7c may be taken together with the nitrogen.....which heteroatoms may be N, O, or S'.
  - Definition of R9 and R10, delete ', which may include a spirocyclic ring'.
- c. Claim 57,
  - Line 1, replace 'A process for preparing' with -- The process of claim 50, further comprising the step of treating intermediate 11 with an acid to form --.
  - Definition of R7b and R7c, lines 3-8, delete 'or R7b and R7c may be taken together with the nitrogen.....which heteroatoms may be N, O, or S'.
  - Page 15, delete 'which comprises.....and treating intermediate 11 with an acid to form the lactone Ia' (i.e. page 15 is deleted in its entirety).
  - Definition of R9 and R10, delete ', which may include a spirocyclic ring'.

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- d. Claim 58, replace page 16 in its entirety with -- The process of claim 57 wherein the lactone has the structure --.
- e. Cancel claim 60.

### ***REASONS FOR ALLOWANCE***

4. The following is an examiner's statement of reasons for allowance:

Claims 47, 48, 50-59 are allowed.

Robl (5686433, PTO-1449) generically discloses a HMG-CoA reductase inhibiting tricyclic compound containing a 7-membered carbocyclic ring. The example compounds (columns 59, 60, Examples 46, 47) have a 5 or 6 membered carbocyclic ring. For the intermediate compounds, a 3-carboxylate or 3-methanol quinoline intermediate compound (column 6, Scheme 1) is described. The instant, however, has an O, N or S -containing 7-membered ring as the central ring of the tricyclic ring system. Absent is the teaching or suggestion to modify Robl's compound to arrive at the instant invention.

Brodfuehrer (US 2003/0018199, having a priority date of 6-6-2001) is not prior art. Although the instant compound (structure 11) is disclosed (page 13, compound 6a), it is not being claimed in the compound claims 1-2 (the (i) moiety of claim 2 is attached to C(O)H to give a compound of formula (D)). Motivation to remove the C(O)H from Brodfuehrer's compound to arrive at the instant intermediate compound is lacking.

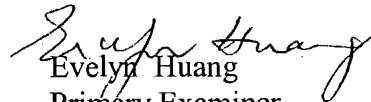
5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 571-272-0693. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Evelyn Huang  
Primary Examiner  
Art Unit 1625

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